

**THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION
CIVIL CASE NO. 1:11-cv-00159-MR-DLH**

**KIMBERLY S. SISK, individually and
as mother and natural guardian of
S.A.S., a minor,**

Plaintiff,

vs.

**ABBOTT LABORATORIES, an
Illinois corporation,**

Defendant.

ORDER

THIS MATTER is before the Court on the Plaintiff's Motion for New Trial [Docs. 236, 249].¹

I. PROCEDURAL BACKGROUND

The Plaintiff Kimberly S. Sisk, individually and as mother, natural guardian and guardian *ad litem* of S.A.S., a minor, brought this action against the Defendant Abbott Laboratories, alleging that the Plaintiff's minor son developed meningitis as a result of consuming contaminated powdered infant formula (PIF) manufactured by the Defendant. On March 14, 2014 through March 17, 2014, this Court held a jury trial on the

¹ The Plaintiff filed a redacted version of her Motion for New Trial as Doc. 249.

Plaintiff's negligence claim. The jury reached a verdict finding that the Defendant was not negligent in its manufacture of the Similac Advance powdered infant formula at issue, nor was the Defendant negligent in failing to provide an adequate warning or instruction with the Similac Advance powdered infant formula. [Doc. 233].

The Plaintiff now moves for a new trial pursuant to Fed. R. Civ. P. 59, arguing that the Court erroneously excluded particular evidence at the trial. [Doc. 236].

II. STANDARD OF REVIEW

Rule 59(a)(1)(A) of the Federal Rules of Civil Procedure provides that “[t]he court may, on motion, grant a new trial on all or some of the issues—and to any party—as follows: (A) after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court.”

The Fourth Circuit has established that “[a] trial court’s exercise of . . . discretion [for evidentiary rulings] is entitled to substantial deference, and will be upheld so long as it is not arbitrary or irrational.” United States v. Myers, 589 F.3d 117, 123 (4th Cir. 2009) (internal quotations and citations omitted). Further, “[u]nless justice requires otherwise, no error in admitting or excluding evidence . . . is ground for granting a new trial. . . . At every stage of the proceeding, the court must disregard all errors and defects that

do not affect any party's substantial rights.” Trademark Properties Inc. v. A & E Television Networks, 422 F. App'x 199, 217 (4th Cir. 2011) (citing Fed. R. Civ. P. 61). This Court can only grant a new trial when it can say “with fair assurance, after pondering all that happened without stripping the erroneous action from the whole, that the judgment was . . . substantially swayed by the error, [therefore] it is impossible to conclude that substantial rights were not affected.” Id. (citing Bank of Montreal v. Signet Bank, 193 F.3d 818, 834 (4th Cir. 1999) (quoting Kotteakos v. United States, 328 U.S. 750, 765 (1946))).

Ultimately, the decision to grant or deny a Rule 59(a)(1)(A) motion is a matter within the Court’s discretion. See Atlas Food Sys. & Servs., Inc. v. Crane Nat’l Vendors, Inc., 99 F.3d 587, 594 (4th Cir. 1996).

III. DISCUSSION

The Plaintiff argues that the Court erred by excluding: “(1) evidence of Abbott’s knowledge of the risk of *E. sakazakii* (“*E. sak*”) in its powdered infant formula, . . . (2) evidence of the scientific consensus that powdered infant formula is associated with *E. sak* infections in infants, (3) evidence of microbiological incidents at both Abbott plants, [and] (4) Dr. Jason’s opinions regarding what information should be on Abbott’s label.” [Doc. 236 at 1]. Notwithstanding the Plaintiff’s hyperbolic summary of the issues,

the Plaintiff argues with regard to the first three issues that the Court improperly excluded certain exhibits from evidence on the grounds that the Plaintiff had laid an insufficient foundation for admission. These exhibits and Dr. Jason's opinion are addressed herein.

A. Exhibit 82

The Plaintiff first argues that the Court should have admitted Exhibit 82, which was an email message showing on its face that it was directed to the members of the International Formula Council ("IFC"). [Doc. 238-2 at 2-13]. Attached to the email is a letter from Robert C. Gelardi and Mardi K. Mountford of the IFC to a doctor of the World Health Organization ("WHO"). [Id.]. The letter references ten attachments, two of which purport to be attached to the email. [Id.]. The Plaintiff argues that this exhibit should have been admitted through the testimony of Dr. Donnelly, who testified that he received it. [Doc. 237-3 at 2-4]. The Plaintiff asserts that it is admissible because it "demonstrate[s] Abbott's state of knowledge at the time concerning not only the association between powdered infant formula and *E. sakazakii*, but also the number of times it could be located in both finished product and environmental samplings." [Doc. 238 at 3]. Dr. Donnelly testified that among the other people listed as intended recipients of the email are three Abbott employees, but no evidence was offered to

show that any of them received it. [Doc. 237-3 at 3-4]. The Plaintiff also argues that one of the attachments, a survey, should have been admitted as a business record. [Id.]. The Plaintiff makes no argument as to how the Plaintiff's substantial rights were prejudiced or how the outcome of the case was swayed by the Court's exclusion of Exhibit 82.

Exhibit 82 was excluded because the Plaintiff failed to lay the proper foundation to introduce the exhibit for the non-hearsay purpose of showing notice to Abbott. A statement that is offered to show notice rather than to seek to prove the truth of the matter asserted is admissible as non-hearsay. See United States v. Cone, 714 F.3d 197, 219 (4th Cir. 2013) (allowing emails to be admitted for the non-hearsay purpose of showing that the defendants were on notice regarding the type of goods being sold). Federal Rule of Evidence 602 establishes that a witness "may testify to a matter only if evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter." Here, the Plaintiff failed to establish that Abbott employees received the email message or the survey. Rather, the Plaintiff attempted to prove notice to Abbott employees through the testimony of Dr. Donnelly, who was a recipient of the email message but was *not* an Abbott employee. [Doc. 242-2 at 8-10]. As the Court noted at trial, the mere fact that the names of Abbott employees were listed on

the email document does not establish notice to those persons. [Doc. 242-2 at 10, Tr. 26:17-19].

Further, the Plaintiff asserts that Exhibit 82 “is obviously a business record.” [Doc. 238 at 3]. Federal Rule of Evidence 803(6) allows the admission of business records as a hearsay exception, where such records are authenticated by certification of the custodian or other qualified person according to Fed. R. Evid. 902(11). See United States v. Laquerre, 119 F. App’x 458, 460-61 (4th Cir. 2005). Here, the Plaintiff’s counsel merely stated at trial that he claimed Exhibit 82 to be a business record, [Doc. 242-2, Tr. 22:14], yet the Plaintiff made no attempt to establish any of the foundational criteria set out in Rule 803(6). Thus, Exhibit 82 was properly excluded by the Court.

Even if the Court had erred by excluding Exhibit 82, the Plaintiff has made no showing that such an error would have affected her substantial rights. See Trademark Properties Inc., 422 F. App’x at 217 (citations omitted). Therefore, the Plaintiff’s first assignment of error is without merit.

B. Exhibits 95, 96, and 84

The Plaintiff next argues that the Court should have admitted Exhibits 95, 96, and 84, to serve as “[e]vidence of the scientific consensus that powdered infant formula is associated with *E. sakazakii* infections in

infants.” [Doc. 238 at 4]. Once again, however, the Plaintiff makes no argument as to how her substantial rights were prejudiced or how the outcome of the case was swayed by the Court’s exclusion of such exhibits.

Exhibit 95 purports to be an IFC email to IFC members including Abbott employees, attaching an “Advance Proof Copy” of the 2004 WHO report. [Doc. 238-4]. Exhibit 96 purports to be the WHO 2004 report. [Doc. 237-8]. The Plaintiff argues that Exhibit 95 is similar to Exhibit 82 and should have been admitted for the non-hearsay purpose of showing notice to Abbott. [Doc. 238 at 5]. As with Exhibit 82, however, the Plaintiff failed to present any evidence of receipt by Abbott. Thus, there was an insufficient foundation for admission for this non-hearsay purpose. The Court also notes that the Plaintiff’s counsel failed to make any argument at trial regarding Exhibit 95 being offered to show notice. [Doc. 242-2 at 12].

Further, the Plaintiff argues that the point of Exhibit 96 was “to establish that Dr. Jason and the WHO were in agreement.” [Doc. 238 at 5]. However, to establish such agreement, a foundation must be laid that this document is, in fact, a statement of WHO. The Plaintiff asserts that Exhibit 96 is “self-authenticating for this purpose,” [Doc. 238 at 5], but makes no attempt to argue how the document comes within Rule 902(2). Moreover, offering the document to show WHO’s “agreement” with Dr. Jason makes

some unnamed person (or persons) at WHO to be non-testifying expert(s) who are not subject to cross examination. Such an out-of-court opinion would not be admissible under Rule 703, however, even if Dr. Jason agreed with it. In addition, the Plaintiff's counsel made no such arguments at trial. This is simply a new theory offered after the fact. Thus, such an argument is not cognizable on a Rule 59 motion.

Exhibit 84 purports on its face to be an IFC document containing statements regarding the "risk profile" of *E. sak* and powdered infant formula. [Doc. 238-3]. The Plaintiff's counsel argues that he laid the proper foundation for Exhibit 84 and also for Exhibit 95 and Exhibit 96 according to Rule 703. [Doc. 238 at 6]. Rule 703 establishes that if the bases of an expert's opinion "would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury *only if* their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect." Fed. R. Evid. 703 (emphasis added). The Court specifically instructed the Plaintiff's counsel regarding Rule 703 and gave him the opportunity to apply Rule 703 in order to enable the Court to conduct its necessary weighing analysis for the admission of evidence used by experts. [Doc. 242-1 at 29-36, Tr. 149:1-158:9]. The Plaintiff's counsel, however, failed to show the Court how the probative value of

Exhibit 84, Exhibit 95, or Exhibit 96 substantially outweighed their prejudicial effect. Rather, the Plaintiff's counsel merely established that Exhibit 84 was relied upon by Dr. Jason, and that *she felt* the document and Exhibit 96 would be helpful to the jury.² [Doc. 242-1 at 29-30, Tr. 149:17-150:4; Doc. 242-1 at 36-38, Tr. 158:11-160:9]. Thus, the Court properly excluded Exhibit 95, Exhibit 96, and Exhibit 84 as inadmissible according to the Rule 703 requirements.

Even if the Court had erred by excluding Exhibit 84, Exhibit 95, and Exhibit 96, the Plaintiff has made no showing that such an error would have affected her substantial rights. See Trademark Properties Inc., 422 F. App'x at 217 (citations omitted). Therefore, the Plaintiff's second assignment of error is overruled.

C. Exhibits 43, 133, and 134

The Plaintiff next argues that the Court should have admitted Exhibits 43, 133, and 134. [Doc. 238 at 6]. These exhibits were excluded because the Plaintiff did not establish their relevance. [Doc. 238 at 6]. Again, the Plaintiff fails to demonstrate how her substantial rights were prejudiced or

² The Court noted to the Plaintiff's counsel during the trial that he may have laid a foundation as to the first element required for Rule 703 evidence to be admitted, but instructed him that he had "absolutely done nothing as to the second element." [Doc. 242-1, Tr. 151:9-16].

how the outcome of the case was swayed by the Court's exclusion of such exhibits.

Each of these exhibits was a Nonconforming Exception Report (NER) indicating batches of formula which had been rejected at Abbott's Casa Grande and Sturgis plants due to microbiological contamination. [Docs. 238-1, 238-5, 238-6]. Federal Rule of Evidence 401 establishes that evidence "is relevant if (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Further, Federal Rule of Evidence 403 states that the court "may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."

When the Plaintiff sought the admission of Exhibit 43 and Exhibit 134 concerning Abbott's Sturgis facility, the Court sustained Abbott's relevance objection, particularly due to the significant time interval between the Sturgis incident and the date of the manufacture of the formula at issue in this case. [Doc. 242-2 at 27, Tr. 94:18-23]. The Plaintiff failed to demonstrate that the events recorded in either Exhibit 43 or Exhibit 134 were probative of any circumstances surrounding the manufacture of the

formula at issue in this case. In addition to the substantial lapse of time, the Plaintiff produced nothing to show a similarity of circumstances between the events recorded and the manufacturing of the subject product.

The Plaintiff's counsel stated that Exhibit 133 was being introduced to show "how the testing changed." [Doc. 242-2 at 20, Tr. 64:25]. Federal Rule of Evidence 407 establishes that "evidence of subsequent measures is not admissible to prove negligence, culpable conduct, a defect in a product or its design, or a need for a warning or instruction." The Court properly noted that there were "two substantial obstacles" to the admission of Exhibit 133. [Doc. 242-2 at 23, Tr. 67:5-9]. One such obstacle was Rule 403, due to the long time interval that had passed between this NER at the Casa Grande facility and the events of this case. The other such obstacle was Rule 407, due to the exhibit's disclosure of a subsequent remedial measure by the change in testing. [Id.]. The Plaintiff failed to overcome either obstacle in seeking to admit Exhibit 133, and thus the Court properly excluded it from evidence.

As noted previously, even if this Court had erred by excluding Exhibit 43, Exhibit 133, and Exhibit 134, the Plaintiff has made no showing that such an error would have affected her substantial rights. See Trademark

Properties Inc., 422 F. App'x at 217 (citations omitted). Thus, the Plaintiff's third assignment of error is without merit.

D. Dr. Jason's Labeling Opinion

Finally, the Plaintiff contends that the Court erred by not allowing Dr. Jason to testify regarding her opinion of what information should have been on Abbott's label. [Doc. 238]. Particularly, the Plaintiff notes that the "Court determined . . . that she [Dr. Jason] was not qualified to offer any opinions regarding the information that Abbott should have placed on its label." [Doc. 238 at 7]. Once more, the Plaintiff fails to demonstrate how her substantial rights were prejudiced or how the outcome of the case was swayed by the Court's exclusion of such exhibits.

Prior to offering any expert testimony on a subject, Federal Rule of Evidence 702 establishes that the witness must be "qualified as an expert by knowledge, skill, experience, training, or education." In this case, the Plaintiff laid the proper foundation to qualify Dr. Jason to testify as an expert in the fields of epidemiology, pediatrics, and infectious disease. [Tr. 97:19-20]. The Plaintiff's counsel stated to the Court that "later when we get to the label part, we can do that separately because it is a different issue." [Doc. 242-1 at 6]. The Plaintiff's counsel failed, however, to qualify Dr. Jason as an expert in labeling before proceeding to ask her questions

regarding labeling. The Court instructed the Plaintiff's counsel that such questioning was beyond the scope of what Dr. Jason had been qualified for, yet the Plaintiff's counsel took no further steps to attempt to qualify Dr. Jason as a labeling expert. [Doc. 242-1 at 43]. Thus, the Court properly excluded the questioning of Dr. Jason regarding labeling in this case.

The Plaintiff also never made an offer of proof as to what Dr. Jason's labeling opinion would have been. As such, there is no basis on which the Court could determine how such opinion could possibly have affected the outcome of the case.

The Plaintiff's fourth assignment of error is thus overruled.

IV. CONCLUSION

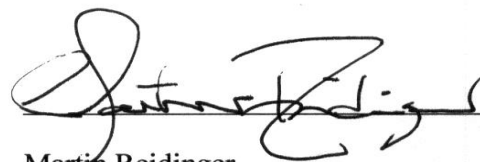
Upon careful consideration of the Plaintiff's motion, the Court concludes that each of the challenged evidentiary rulings was proper. The substantial rights of the Plaintiff were not prejudiced, and thus the Plaintiff is not entitled to a new trial.

ORDER

IT IS, THEREFORE, ORDERED that the Plaintiff's Motion for a New Trial [Docs. 236 and 249] is **DENIED**.

IT IS SO ORDERED.

Signed: October 20, 2014


Martin Reidinger
United States District Judge

